

REMARKS/ARGUMENT

Claims 51-59 were pending prior to this amendment.

Claims 51-55 and 56-59 are rejected as obvious under 35 USC 103 over Pathak (US 6,113,944) in combination with Benneker (US 5,874,447) and Takedo (US 5,486,365).

Claim 58 has been indicated as containing a typographical error at the end thereof.

Claim 58 is amended.

Claims 51-59 are presented for reconsideration.

The Examiner has rejected the claims over Pathak in view of Benneker and Takedo. The Examiner has not understood Applicant's prior argument. In that argument, Applicant was stating that Pathak states that surprisingly the tablets formed there allow for the absence of microcrystalline cellulose and that in general, the use of calcium phosphates without microcrystalline cellulose was not suitable. Thus, Applicant here was stating that this is a clear teaching that the invention taught in Pathak is actually limited to the specific formulations in Pathak and cannot be extended to a teaching to modifications of Pathak with an expectation of success. As such, the entire prima facie case falls and the present invention is patentable. Applicant respectfully requeststhe Examiner to revisit this position and pass the case to allowance.

In the present amendment Applicant has corrected the typographical error kindly pointed out by the Examiner.

On September 20, 2007, Applicant contacted the Examiner by telephone to discuss a potential issue concerning incorporation by reference of the properties of A-TAB mentioned in Example 1 of the Specification in order to rely on those properties to distinguish the Takedo reference. The Examiner indicated that while the copying of those properties into the specification and claims would not be new matter, at this stage of the prosecution, this would raise new issues requiring further search and therefore would not be entered after final, but that a continuation or Request for Continued Examination would be appropriate. Thus, this amendment accompanies a Request for continued Examination, and entry is respectfully requested.

The Amendment to the Specification are merely the insertion that A-TAB, which is calcium hydrogen phosphate anhydrous, a.k.a. dicalcium phosphate anhydrate, is in the form of plate shaped crystals, generally of 15-30 microns or agglomerates thereof. The original Example 1 mentioned that the calcium hydrogen phosphate anhydrous was A-TAB. Enclosed herewith is a printout of 2 records of the US Patent and Trademark Office Trademark Database showing A-Tab to be in use from as early as October 1985, and currently owned by Innophos, Inc. Also enclosed is a printout from the Innophos website concerning A-TAB and shows that “calcium hydrogen phosphate” is one of the chemical synonyms used for A-TAB. Also enclosed is a letter from Dr. Robert Finn, Sr. Staff Scientist at Innophos, Inc, providing details about a-Tab. In that letter, undated, but written in September 2007, Dr. Finn indicates that A-Tab has rhombic plate shaped crystals generally of 15-30 microns which can form agglomerates resulting in clusters of larger size. This indication of crystal size and shape is the subject matter entered into the application by the present amendments. With the above supporting documentation, Applicant submits that the amendments do not present any new matter, but merely incorporate the inherent properties of the A-TAB mentioned in the original text of Example 1. As such, Applicant submits that he Amendments should be entered and the claims considered in light thereof.

Turning to the rejections of the claims over the combination of Pathak, Benneker, and Takedo, the Examiner concedes that neither Benneker nor Pathak mention nor make obvious the use of calcium hydrogen phosphate anhydrous in their tablets, either alone or in combination. The Examiner relies on Takedo for this aspect. However, Takedo refers to a specialized precipitated form of calcium hydrogen phosphate, and not the form that is represented by A-TAB. Note Takedo, column 1, lines 16-23:

Since calcium hydrogen phosphate is non-hygroscopic, inert, non-reactive with medicines, and does not discolor formulations, attempts have been made to utilize it as an excipient for such items as medicines, cosmetics, and foods. However, since calcium hydrogen phosphate takes the form of sheet-like crystalline granules of 10  $\mu\text{m}$  or more and therefore features inferior binding properties, unsuitable as an excipient.

Then in discussing the invention in the Takedo reference, Takedo states at col. 3, lines 35-38:

Since the scale-like calcium hydrogen phosphate has entirely different physical properties than conventional calcium hydrogen phosphate, it can be used as an excipient independently or in conjunction with other excipients.

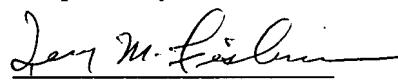
Note that the Takedo reference has a priority date of September 17, 1993, so that A-TAB, being used at least since 1985, was already one of the conventional prior art calcium hydrogen phosphates thereto. Thus, the Takedo reference is teaching that sheet-like (or "plate") crystals of 10 microns and larger are not suitable as excipients. Since A-TAB and the calcium hydrogen phosphate anhydrous materials to which the claims are now limited require that the crystals be plates of generally 15-30 microns or agglomerates thereof, the Takedo reference teaches away from the present invention, not toward it. As such, the Examiner's prima facie case is no longer

made out. Thus, the outstanding rejections are overcome, and Applicant respectfully requests that the instant application be passed to issue.

As such, a Notice of Allowance is respectfully requested.

Respectfully submitted,

Date: October 15, 2007



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**TARR Status** **ASSIGN Status** **TDR** **TTAB Status** (*Use the "Back" button of the Internet Browser to return to TESS*)

**Typed Drawing**

**Word Mark** A-TAB  
**Goods and Services** IC 001. US 001 005 006 010 026 046. G & S: anhydrous dicalcium phosphate for use in tabletting. FIRST USE: 19851007. FIRST USE IN COMMERCE: 19851007

**Mark Drawing Code** (1) TYPED DRAWING

**Serial Number** 74687971

**Filing Date** June 7, 1995

**Current Filing Basis** 1A

**Original Filing Basis** 1A

**Published for Opposition** January 16, 1996

**Registration Number** 1967070

**Registration Date** April 9, 1996

**Owner** (REGISTRANT) Rhone-Poulenc Inc. CORPORATION NEW YORK Black Horse Lane Monmouth Junction NEW JERSEY 085435266

(LAST LISTED OWNER) INNOPHOS, INC. CORPORATION DELAWARE 259 PROSPECT PLAINS ROAD CRANBURY NEW JERSEY 08512

**Assignment Recorded** ASSIGNMENT RECORDED

**Type of Mark** TRADEMARK

**Register** PRINCIPAL

**Affidavit Text** SECT 8 (6-YR). SECTION 8(10-YR) 20051227.

**Renewal** 1ST RENEWAL 20051227

**Live/Dead Indicator** LIVE

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### Typed Drawing

Word Mark	A-TAB
Goods and Services	(CANCELLED) IC 001, US 006. G & S: ANHYDROUS DICALCIUM PHOSPHATE FOR USE IN TABLETING. FIRST USE: 19851007. FIRST USE IN COMMERCE: 19851007
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	73565174
Filing Date	October 25, 1985
Current Filing Basis	1A
Original Filing Basis	1A
Published for Opposition	March 4, 1986
Registration Number	1394542
Registration Date	May 27, 1986
Owner	(REGISTRANT) STAUFFER CHEMICAL COMPANY CORPORATION DELAWARE WESTPORT CONNECTICUT 068810850
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	PAUL J. JUETTNER
Prior Registrations	1136524;1256467;1318808
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	DEAD
Cancellation Date	November 30, 1992

## A-TAB (1/2)

### PRODUCT DATA SHEET ORG FP ATAB APR2007

<u>IDENTIFICATION</u>	CAS N° [7789-77-7]	
<u>SYNONYM</u>	Dibasic Calcium Phosphate Anhydrous Phosphoric acid, calcium salt (1:1) Calcium Phosphate, Anhydrous (1:1) Calcium Hydrogen Phosphate Anhydrous Calcii hydrogenophosphas anhydricus	
<u>EMPIRICAL FORMULA</u>	CaHPO <sub>4</sub>	
<u>MOLECULAR WEIGHT</u>	$M_r = 136.1$	
<u>PHYSICO-CHEMICAL PROPERTIES</u>	White, odourless and tasteless granules. Practically insoluble in cold water and in ethanol (96 per cent). It dissolves in dilute hydrochloric acid and in dilute nitric acid.	
<u>APPLICATIONS</u>	Used as excipient in the manufacture of medicinal and nutraceutical products and as a source of calcium and phosphorus in nutritional supplements.	
<u>SPECIFICATIONS</u>	The specifications below are the harmonized specifications in force in the EU since April 1, 2007 and the US as of December 1, 2007 (USP 30, S2) – Considering some specifications are not harmonized, our sales specifications are based on the most restrictive ones	
Specification items	Limits	Comment (non harmonized attributes)
Assay (as CaHPO <sub>4</sub> · 2 H <sub>2</sub> O)	98.0 – 103.0 %	
Loss on Ignition	6.6 – 8.5 %	
Chlorides	0.25 % max	
Fluorides	50 ppm max.	Ph.Eur. limit is 100 ppm max
Sulphates	0.5 % max	
Arsenic	3 ppm max.	Ph.Eur. limit is 10 ppm max
Lead (FCC)	2 ppm max.	Not in USP nor in Ph.Eur.
Heavy metals (as Pb)	0.003 % max.	Ph.Eur. limit is 40 ppm max
Carbonate Passes test		
Barium Passes test		
Acid insoluble substances	0.2 % max	
Iron	400 ppm max	Not a USP requirement
Particle Size (wet sieving)		
On 20 # ( 850 µm)	1 % max	Not in USP nor in Ph.Eur.
On 100 # ( 150 µm)	40 % min	Not in USP nor in Ph.Eur.
Through 200 # ( 75 µm)	25 % max	Not in USP nor in Ph.Eur.
Through 325 # ( 45 µm)	5 % max	Not in USP nor in Ph.Eur.

## A-TAB (2/2)

<u>TYPICAL PROPERTIES</u>	pH (20 % slurry) 5 Bulk Density 0.80 g/ml (50 lbs/ft <sup>3</sup> ) Calcium content 29.1 % Phosphorus content 22.6 % Lead 0.25 ppm Particle size (wet sieving) On 20 # ( 850 µm) 0 % Through 100 # ( 150 µm) 35 % Through 200 # ( 75 µm) 10 % Through 325 # ( 45 µm) 3 %
<u>REGULATORY / QUALITY</u>	Regulatory support is provided to assist our customers in their registration process.  The following declarations can be downloaded on <a href="http://www.innophos.com/certs.asp">http://www.innophos.com/certs.asp</a>
	Allergen: Free of Allergens GMO: Free of Genetically Modified Organisms Halal: Product Conforms to Halal Standards ISO: ISO-9001: 2000 (NSH-ISR) Kosher: Product Conforms to Kosher Standards NAFTA: Product Qualifies for the North-American Free Trade Agreement NSF1 and NSF2 International – Product conforms to NSF Standard 60 BSE/TSE: No materials of animal origin are used Residual Solvents: The product is free of Residual Solvents
<u>PACKAGING</u>	25 kg net weight paper bags
<u>TRANSPORT</u>	<input type="checkbox"/> INLAND International Legislation (RID-ADR)   Not regulated <input type="checkbox"/> SEA FREIGHT (OMI) <input type="checkbox"/> AIR FREIGHT (IATA)
<u>STORAGE CONDITIONS</u>	Keep the product in the original unopened container away from moisture and heat, in normal pharmaceutical warehousing conditions. Re-test date: 3 years
<u>SAFETY INSTRUCTIONS</u>	Please consult the material safety data sheet, downloadable on <a href="http://www.innophos.com">http://www.innophos.com</a>
<u>WARNING TO USERS</u>	The information contained in this document is given in good faith based on our current knowledge. It is only an indication and is in no way binding, particularly as regards infringement or prejudice to third party rights through the use of our products. We guarantee that our products comply with our sales specifications. This information must on no account be used as a substitute for necessary prior tests which alone can ensure that a product is suitable for a given use. Users are responsible for ensuring compliance with local legislation and for obtaining the necessary certifications and authorizations. Users are requested to check that they are in possession of the latest version of this document and we are at their disposal to supply any additional information.



**Innophos Research and Development Center**

Innophos produces A-Tab ®, an anhydrous dicalcium phosphate as an excipient for pharmaceutical products. A-Tab ® is a crystalline material which grows into rhombic plate shaped crystals. Individual crystals vary in size, but most are between 15-30 um in length when measuring the longest axis. These plates form agglomerates of larger clusters with the major fraction of particles between 74 and 150 um (200 and 100 mesh). The overall particle size specification is 1% maximum on 20 Mesh, 40% minimum through 100 Mesh, 25% maximum through 200 Mesh, and 5% maximum through 325 Mesh. The agglomerated crystals are not considered very porous, having a typical surface area of 8-15 m<sup>2</sup>/g. Some other typical properties and specifications of A-Tab ® can be found at [www.Innophos.com](http://www.Innophos.com) which is the source of the charts seen below.

**Typical Properties**

pH	5
Bulk Density	50
Phosphorus	22.6%
Calcium	29.1%
Lead	< 0.25 ppm
Compressibility, kp range	25 - 38
Insoluble	in Alcohol
<b>Specifications</b>	
Assay	98.0% min. - 105% max.
Loss on Ignition	7.0 min. - 8.5% max.
Arsenic	3 ppm max.
Fluoride	0.005% max.
Heavy Metal	(as Pb) 0.003% max.
Lead	2 ppm max.
Chloride	0.25% max.
Carbonate	Passes Test
Sulfate	0.5% max.
Barium	Passes Test
Acid Insolubles	0.2% max.

Regards,

Robert C. Finn, PhD

Sr. Staff Scientist, Innophos. Inc.